



Immunization Advisory Committee:

Criteria for Reviewing Antigens for Potential Inclusion in WAC 246-100-166

Adopted June 14, 2006

Washington State Board of Health

PO Box 47990

Olympia, WA 98504-7990

Phone: 360-236-4110

Fax: 360-236-4088

Email: wsboh@doh.wa.gov

Web: www.sboh@doh.wa.gov

IMMUNIZATION ADVISORY COMMITTEE:
CRITERIA FOR REVIEWING ANTIGENS FOR POTENTIAL INCLUSION IN WAC 246-100-166

PURPOSE: The Washington State Board of Health (SBOH) established the Immunization Advisory Committee (IAC) in December 2005 to recommend criteria that a Technical Advisory Group (TAG) could use to evaluate which antigens¹ (or diseases) to include in WAC 246-100-166 (Immunization of child care and school children against certain vaccine preventable diseases).

RATIONALE: Many new vaccines for children and young adults are expected to be available over the next few years. A number of these vaccines will end up on the Advisory Committee on Immunization Practices (ACIP) *Recommended Childhood and Adolescent Immunization Schedule*. The board will face complex decisions about which vaccines to include in the child care/school immunization rule (WAC 246-100-166). Factors other than those considered by the ACIP will need to be considered to address the unique needs of our state. The Board believes that approaching this decision using rational criteria is the best method for protecting children and the community at large while balancing the interests of parents and families.

WHO: Immunization stakeholders from the fields of public health, school health, medicine, child advocacy, and medical ethics as well as consumers (parents) used consensus to identify the best criteria for determining which vaccines to include.

RESULTS: The IAC met three times to develop the recommendations described in this report. In addition, between the second and third meeting of the IAC a TAG further refined the criteria and tested them against the pertussis antigen. The TAG comprised representatives from the fields of public health, primary care, epidemiology, and medical ethics. The IAC reviewed and further refined the TAG's work at its final meeting in March 2006. These criteria were presented to the SBOH at the April 12, 2006 meeting. The board adopted the report as an interim report and asked that the TAG be re-convened to further refine the criteria and to test them against three antigens (pertussis, tetanus, and diphtheria). The TAG met on May 17, 2006. The results of the TAG deliberations were presented to and adopted by the board on June 14, 2006.

Framework for Establishing the Criteria

John Stuart Mill in *On Liberty* wrote, "The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant." This thesis has become known as the harm principle. The IAC endorsed the harm principle and interpreted it to mean that vaccine requirements for children entering child care and/or school are justifiable when without them:

¹ Antigen means a substance, foreign to the body, that stimulates the production of antibodies by the immune system. Antigens include foreign proteins, bacteria, viruses, pollen and other materials.

IMMUNIZATION ADVISORY COMMITTEE:
CRITERIA FOR REVIEWING ANTIGENS FOR POTENTIAL INCLUSION IN WAC 246-100-166

- An individual's decision could place others' health in jeopardy
- The state's economic interests could be threatened by the costs of care for vaccine preventable illness, related disability, or death, and by the cost of managing vaccine preventable disease outbreaks
- The state's duty to educate children could be compromised

Assumptions for Establishing the Criteria

The IAC made two assumptions while drafting criteria: (1) some kind of process exists to opt out of immunization requirements by children attending either child care centers and school; and (2) that vaccine(s) containing the antigen are accessible and that cost is not a barrier. (Under the current system of universal purchasing, this would mean that the state purchases and distributes the vaccine.)

Process for Reviewing Antigens for Potential Inclusion in WAC 246-100-166

1. The Board reviews the proposed antigen to determine whether the two assumptions listed above have been met, whether there is adequate information specific to Washington State with which to evaluate the antigen against the nine criteria below, and whether there is some likelihood, based on a preliminary review, that the antigen might meet those criteria. Generally speaking the Board will wait for two years, after the Department of Health has made the vaccine containing the antigen(s) available to providers in Washington State. (Under the current system of universal purchasing, this would mean that the state has purchased and distributed the vaccine for two years.) However, if the Board determines there is a pressing public health need or other substantial reason, the Board may elect to forgo this waiting period.
2. If the Board determines that these preconditions have been met, the Board sponsor will establish a TAG to review the antigen against the nine criteria. For antigens that are part of a combination vaccine, each antigen will be considered separately against the criteria. The TAG must include representatives from the fields of public health, primary care, epidemiology, and medical ethics. At the discretion of the board sponsor, either a wider IAC or a TAG sub-committee can be formed (this expanded body could also include consumers [parents] and representatives from the fields of school health, school administration, child care, child advocacy, immunization administration, and others). In addition to providing the TAG with current literature and other relevant information such as survey data, the Board will ask the Department of Health to supply any current information about the disease that is specific to Washington State and provide it to the TAG for consideration.
3. All nine criteria must be considered by the TAG; however, the criteria are not necessarily weighted equally. Members of the TAG are expected to rely on their professional and scientific judgment as well as available data when applying the criteria. The TAG formulates a recommendation to the Board on whether it

should initiate formal rule making that could result in the antigen/disease being added to WAC 246-100-166 or other change to the rule.

4. The TAG recommendation, accompanied by a brief summary of the TAG's deliberations on each of the nine criteria, goes to the Board for consideration and possible action.

The Three Categories of Criteria

The IAC grouped criteria into three categories: vaccine effectiveness, disease burden, and implementation.

Nine Criteria to Consider in Evaluating Antigens

I. Criteria on the effectiveness of the vaccine

1. A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices and included on its Recommended Childhood & Adolescent Immunization Schedule.
2. The antigen is effective as measured by immunogenicity² and population-based prevention.
3. The vaccine containing this antigen is as cost effective from a societal perspective as other vaccines used to prevent the diseases included in WAC 246-100-166.
4. Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of side effects.

II. Disease Burden Criteria

5. The vaccine containing this antigen prevents disease(s) with significant morbidity and/or mortality in at least some sub-set of the population.
6. Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.

III. Implementation Criteria

7. The vaccine is acceptable to the medical community and the public.
8. The administrative burdens of delivery and tracking of vaccine containing this (these) antigen(s) are reasonable.
9. The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.

² Immunogenicity means the ability of an antigen or vaccine to stimulate the body to produce an immune response. Vaccines often include antigens that stimulate an immune response to a particular disease but not necessarily the same as the organism that would cause the disease.

Explanations for the Nine Criteria

I. Criteria on the effectiveness of the vaccine

1. A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices (ACIP) and included on its recommended childhood immunization schedule.

The vaccine must have been recommended by the ACIP. The ACIP reviews licensed vaccines. It makes recommendations for newly licensed vaccines and regularly updates its recommendations. Its process includes: (1) a review of the Food and Drug Administration (FDA) labeling/package inserts for each vaccine; (2) a thorough review of the scientific literature (both published and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent, with consideration of the relevance, quality, and quantity of published and unpublished data; (3) an assessment of cost effectiveness; (4) a review of the morbidity and mortality associated with the disease in the population in general and in specific risk groups; (5) a review of the recommendations of other groups; and (6) a consideration of the feasibility of vaccine use in existing child and adult immunization programs. Feasibility issues include (but are not limited to) acceptability to the community, parents, and patients; vaccine distribution and storage; access to vaccine and vaccine administration; impact on the various health care delivery systems; population distribution effects; and social, legal, and ethical concerns.

2. The antigen is effective as measured by immunogenicity and population based prevention.

In the clinical development of a vaccine, the efficacy of the vaccine is studied using FDA-approved research protocols that evaluate whether a vaccine protects individuals from contracting the disease in population-based studies or generates an immunologic response (immunogenicity) comparable to vaccines that have been shown to be effective in preventing disease. More information about its population-based effectiveness is gained from large trials and community-based analyses after FDA approval.

3. The vaccine containing this antigen is as cost effective from a societal perspective as other vaccines used to prevent the diseases included in WAC 248-100-166.

Immunizations are the most cost-effective clinical preventive service for children, saving both lives and money. Vaccines may be cost effective without being cost saving. In other words, the direct costs of some vaccines (e.g. antigen, storage, administration) balanced against direct savings (e.g. medical care, disability, death) may not result in net savings. In some cases, societal or indirect costs (e.g. lost productivity of care takers of ill children) will also need to be taken into consideration. These costs are much harder to quantify. Not all vaccines recommended by the ACIP are cost saving or equally effective, so some determination of the vaccine's relative cost

IMMUNIZATION ADVISORY COMMITTEE:
CRITERIA FOR REVIEWING ANTIGENS FOR POTENTIAL INCLUSION IN WAC 246-100-166

effectiveness may need to be made for comparison purposes when applying the criteria.

4. Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of side effects.

Vaccinations are not without side effects. The known risks associated with each vaccine (or antigen) must be balanced against the risks of the disease. Vaccine safety will be evaluated using research and reports from: pre-licensure, the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) project.

II. Disease Burden Criteria

5. The vaccine containing this antigen prevents diseases with significant morbidity and/or mortality implications in at least some sub-set of the population.

Vaccines have the potential to reduce, or in some cases even eliminate, diseases that can result in serious illness, long-term disability, or death. For example, before the measles immunization was available, nearly everyone in the United States contracted measles and an average of 450 measles-associated deaths were reported each year between 1953 and 1963. The morbidity/mortality burden of measles was not equal for all members of the population. Examples of significant morbidity measures include rates of hospitalizations, long-term disability, disease incidence, and disproportionate impact.

6. Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.

Having some proportion of the population vaccinated with the antigen helps to stem person to person transmission of the disease (i.e, herd immunity). Even community members who are not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has less opportunity to spread within the community. Vaccinating children in school and/or child care centers can increase the percentage of children in these groups who are immune and thus reduce the risk of outbreaks of the disease in these groups and in the community at large.

III. Implementation Criteria

7. The vaccine is acceptable to the medical community and the public.

It is possible to gauge the level of provider acceptance of a vaccine by querying state professional societies such as the Washington Academy of Family Physicians and the Washington State Chapter of the American Academy of Pediatrics. While there is generally a good correlation between the levels of physicians' and the general public's acceptance of particular vaccines, a growing minority of the public has not accepted some

IMMUNIZATION ADVISORY COMMITTEE:
CRITERIA FOR REVIEWING ANTIGENS FOR POTENTIAL INCLUSION IN WAC 246-100-166

recommended vaccines. Therefore, public acceptance of specific vaccines needs to be considered. Most parents today have never seen a case of diphtheria, measles, or other once-common diseases now preventable by vaccines. As a result, some parents wonder why their children must receive shots for diseases which seemingly no longer exist in Washington communities. Myths and misinformation about vaccine safety abound and can make it difficult for parents who are trying to make sound decisions about their children's health care. Adding an antigen/disease to WAC 246-100-166 related to a vaccine with poor provider or public acceptance would likely be resisted. Postponing the regulation until there is greater approval of the vaccine would assure more effective policy.

8. The administrative burdens of delivery and tracking of vaccines containing this (these) antigen(s) are reasonable.

Many players are involved in implementation when the Board adds a new vaccine WAC 246-100-166 including: the Department of Health, the Department of Social and Health Services, the Office of Superintendent of Public Instruction (OSPI), local health jurisdictions, schools, health plans, and health care providers. For each of these key players, there are issues that affect the feasibility of implementing an immunization recommendation. For example, introduction of a new vaccine can result in schools conducting more parental follow-up and making changes to record and information systems—this in turn can impact school staff workload. Assuring a reasonable burden of work will enhance the effectiveness of the policy. The TAG will consult with affected parties such as OSPI, schools, and child care centers when assessing an antigen against this criterion.

9. The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.

Parents and caregivers are often involved in obtaining vaccines for children. This can include: transporting children to medical appointments, taking time off of work for medical appointments, maintaining the child's immunization records, etc. When a vaccine is required for child care and/or school entry it affects the health decisions that parents make on their child's behalf because parents must, at the very least, take the required vaccine into account.